Standards BoosterPak™ for

Safe Medication Storage

MM.03.01.01

The Joint Commission

Standards BoosterPak for
Safe Medication Storage (MM.03.01.01)

Contents

A. Description of Standard and Implementation Expectations
Section A1: Standard Rationale, Elements of Performance (EPs), Scoring Categories, Implementation Suggestions

Program: Hospital
Chapter: Medication Management
Standard Number: MM.03.01.01
Standard Text: The hospital safely stores medications.
Rationale: Medication storage is designed to assist in maintaining medication integrity, promote the availability of medications when needed, minimize the risk of medication diversion, and reduce potential dispensing errors. Law and regulation and manufacturers' guidelines further define the hospital's approach to medication storage.

Element of Performance:
2. The hospital stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.
    Note: *This element of performance is also applicable to sample medications.*

Scoring Categories:
Criticality level: Indirect
Documentation required: No
Scoring category (A or C): C
Measure of Success: Yes
Identified risk area: No

Implementation Suggestions:
A process exists for ensuring that medications are stored safely and at the correct temperature according to manufacturers' recommendations. This can be accomplished through the use of automated temperature recording devices or manual reading of temperatures. Staff are aware of the process and what their responsibilities are for monitoring temperatures and for resolving problems related to temperatures that are out of range (for example, Do they adjust the refrigerator/freezer temperature and recheck after a specified interval? When do they involve pharmacy to determine if the medications are still viable? When are facilities staff notified if equipment is malfunctioning? What happens to medications that are stored in a department that is not open on the weekends? How do you assure that the appropriate temperature is maintained? How do you know your process is working?).

Tips:
Because checking temperatures is often assigned to nonlicensed staff, be sure that staff understand who to call and when if problems are identified (for example, Does the C.N.A. notify pharmacy and facilities, or does the C.N.A. notify the manager or charge nurse who then starts the process?). Who supervises the nonlicensed staff to ensure that the task is being completed?

Element of Performance:

3. The hospital stores all medications and biologicals, including controlled (scheduled) medications, in a secured area to prevent diversion, and locked when necessary, in accordance with law and regulation.

    Note 1: *Scheduled medications include those listed in Schedules II–V of the Comprehensive Drug Abuse Prevention and Control Act of 1970.*

    Note 2: *This element of performance is also applicable to sample medications.*

Scoring Categories:

Criticality level: Indirect

Documentation required: No

Scoring category (A or C): A

Measure of Success: No

Identified risk area: No

Implementation Suggestions:

- Narcotics and other scheduled drugs are locked at all times, and narcotic counts are done as required. Visit the Food and Drug Administration (FDA) Web site for a complete listing of scheduled drugs: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1308.
- Define the process for wasting of scheduled drugs—is it being consistently followed by the staff?
- Records of usage are appropriately maintained, and any discrepancies are resolved within the defined time frame.
- Define the resolution process and what happens when the discrepancy cannot be reconciled.
- If automated distribution devices are being used, be sure that access is current and that it is promptly removed when staff transfer or leave the organization.
- If automated distribution devices are being used, be sure that staff are logging out after they have pulled the medications needed to administer in order to prevent someone else from removing narcotics after the staff member has left the device.
- Utilize the report function from automated distribution devices to identify potential diversion, trends in usage, and so forth.

Tips:

- Educate staff on how to identify potential diversion and what process to follow.
- Spot checks of narcotic counts/wastage may help identify problems early.
- Conduct spot checks to ensure that staff have logged off the automated distribution device after they have completed their removal of drugs (*see also* EP 6).

Element of Performance:

4. The hospital has a written policy addressing the control of medication between receipt by an individual health care provider and administration of the medication, including safe storage, handling, security, disposition, and return to storage.
   Note: *This element of performance is also applicable to sample medications.*

Scoring Categories:

Criticality level: Indirect

Documentation required: Yes

Scoring category (A or C): A

Measure of Success: No

Identified risk area: No

Implementation Suggestions:

- The policy addresses whether or not the organization allows staff members to pull medications for more than one patient at a time.
- If that practice is allowed, how does the staff member keep the medications secure and appropriately stored in terms of temperature until the meds are administered? Are fanny packs, lab coats, and/or pouches allowed? If so, how are they kept clean? What happens if the lab coat or fanny pack is removed while medications are still being carried? What is the process if the medication needs to be maintained at a certain temperature?
- During what time frame can the staff member pull medications (how long before the medication is due)?
- The process should be the same throughout the organization. Respiratory therapists should follow the same process as nurses, and so forth.
- What happens to the medications at the end of the shift? Are they returned to stock? Are they returned to pharmacy?

Tips:

- Involve pharmacy, nursing, respiratory care, and anesthesia in the development of the process.

Element of Performance:

5. The hospital implements its policy addressing the control of medication between receipt by an individual health care provider and its administration.

   Note: *This element of performance is also applicable to sample medications.*

Scoring Categories:

Criticality level: Indirect

Documentation required: No

Scoring category (A or C): C

Measure of Success: Yes

Identified risk area: No

Implementation Suggestions:

- Educate the staff on the process and expectations.
- Develop a process to ensure that staff are following the defined processes. If not, why? What in the process is keeping staff from complying?

Element of Performance:

6. The hospital prevents unauthorized individuals from obtaining medications in accordance with its policy and law and regulation.

   Note: *This element of performance is also applicable to sample medications.*

Scoring Categories:

Criticality level: Indirect

Documentation required: No

Scoring category (A or C): A

Measure of Success: No

Identified risk area: No

Implementation Suggestions:

- Review the Centers for Medicare & Medicaid (CMS) definition of medication security—*see* State Operations Manual: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals /downloads/som107_appendixtoc.pdf.
- Determine how medications will be kept secure in your organization.
- Determine who is authorized to access medications and define in policy.
- Depending on state and/or federal law and regulation, this can include nonlicensed personnel. If you are considering this approach, it is best to conduct a risk analysis to be sure the benefits and risks are identified and addressed. All staff should understand the expectations in terms of their responsibilities in keeping medications secure.
- If using automated distribution devices, access must be removed ASAP for staff who are terminated. The process for ensuring that access is removed should be defined by pharmacy and human resources.

Tips:

- Conduct spot checks to see if terminated employees' access has been removed.
- If keypads are utilized to keep medication carts or doors secure, be sure to change the code frequently so that the keys don't become so worn that it is easy to tell what the code is by looking at the keypad.

Element of Performance:

7. All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.

   Note: *This element of performance is also applicable to sample medications.*

Scoring Categories:

Criticality level: Direct

Documentation required: No

Scoring category (A or C): C

Measure of Success: Yes

Identified risk area: Yes

Implementation Suggestions:

- Define the process to ensure that labeling is occurring as required.
- Spot check to ensure that the process is followed.

Element of Performance:

8. The hospital removes all expired, damaged, and/or contaminated medications and stores them separately from medications available for administration.

    Note: *This element of performance is also applicable to sample medications.*

Scoring Categories:

Criticality level: Indirect

Documentation required: No

Scoring category (A or C): C

Measure of Success: Yes

Identified risk area: No

Implementation Suggestions:

- Define the process for managing expired, damaged, and/or contaminated medications.
    - —How do staff determine that a medication is damaged and/or contaminated?
    - —Do staff know where to look for expiration dates and how to read them?
    - —Where will the drugs be stored until sent back to pharmacy?
    - —Is that area secure and will it prevent diversion, and so forth?
- *See also* EP 18 regarding periodic inspections of medication storage areas.
- *See also* MM.03.01.03 regarding the storage of emergency medications, as it is critical that these medications are not expired, damaged, or contaminated in any way.

Tips:

- Highlight the necessity of checking for expired, damaged, and contaminated meds in those areas or carts not accessed on a routine basis.
- Crash carts—it is often helpful to mark the earliest expiration date of meds and supplies (such as defibrillator pads) on the outside of the cart—must be updated whenever meds or supplies are replaced. The carts should be opened at least once per month to look for outdates as well. Don't forget crash carts in outpatient departments, and so forth.
- Malignant hyperthermia carts are frequently found to be outdated or missing the correct number of dantrolene vials—check these frequently as well and be sure that these carts or boxes are easily accessible. For more information visit http://medical.mhaus.org/.

Element of Performance:
9. The hospital keeps concentrated electrolytes present in patient care areas only when patient safety
   necessitates their immediate use, and precautions are used to prevent inadvertent administration.
   (*See also* MM.01.01.03, EP 2.)

Scoring Categories:
Criticality level: Direct
Documentation required: No
Scoring category (A or C): A
Measure of Success: No
Identified risk area: No

Implementation Suggestions:
- Limit where concentrated electrolytes are allowed outside of the pharmacy.
- Define the safety precautions that must be in place to prevent inadvertent administration.
- Define who is allowed to access concentrated electrolytes—what training is provided?
- *See also* EP 18 regarding periodic inspection of medication storage areas.

Tips:
Have requests to store concentrated electrolytes outside of the pharmacy approved by the pharmacy and therapeutics (P&T) committee and provide pharmacy oversight to ensure that the area really does have a critical patient need and that the staff are competent to manage.

Element of Performance:

10. Medications in patient care areas are available in the most ready-to-administer forms commercially available or, if feasible, in unit-doses that have been repackaged by the pharmacy or a licensed repackager.

    Note: *This element of performance is also applicable to sample medications.*

Scoring Categories:

Criticality level: Direct
Documentation required: No
Scoring category (A or C): C
Measure of Success: Yes
Identified risk area: Yes

Implementation Suggestion:

• Medications will be in unit-dose or most ready-to-administer forms in the patient care areas.

Element of Performance:
18. The hospital periodically inspects all medication storage areas.
    Note: *This element of performance is also applicable to sample medications.*

Scoring Categories:
Criticality level: Indirect
Documentation required: No
Scoring category (A or C): C
Measure of Success: Yes
Identified risk area: No

Implementation Suggestions:
• Inpatient and outpatient areas that store medications are included in the periodic inspections.
• A risk assessment will assist in determining frequency and what areas need to be included.

Tips:
• Vary the dates/times of the periodic inspections so units/departments don't "prepare" for the inspection. Promote continuous compliance.
• Engage staff in the process by having someone accompany the person (pharmacist, manager, director) conducting the inspection in order to learn what is inspected and what the expectations are.
• Encourage units/departments to conduct their own inspections in between the required inspections to help maintain compliance.
• Conduct spot checks of narcotic counts, wastes, and so forth.

Section A2: Information About How The Joint Commission Assesses Compliance with the Standard

During individual tracer activity, while moving throughout the organization surveyors will determine what types of medications a patient is receiving. Using this information, surveyors will approach staff on various units and in various departments and ask about the following:
- Where medications, including controlled substances, are stored in the area
- How staff are made aware of special storage requirements for a particular medication; how special storage requirements are monitored, and what the process is when storage is problematic. For example, when a temperature is out of range, what should be done? Who should be notified? When should pharmacy get involved to determine if the medications are still usable?
- Procedures for accessing medications
- Procedures in place to keep medications secure
- Individuals responsible for monitoring medications and removing those expired, damaged, and/or contaminated
- Procedures for (and the individuals responsible for) inspecting medication storage areas
- How well they are adhering to policy and procedure; how they measure performance; how frequently they assess their performance

The above-noted medication storage topics will be explored with pharmacy staff as well.

While in the pharmacy, the staff will be asked additional questions about the following:
- Procedures for tracking controlled substances from receipt to dispensing to administration, and to disposal
- Analyzing the tracking records for controlled substances and the reconciling process
- The processes in place to minimize the diversion of controlled substances and how the organization knows these processes are working
- The security features of automated medication distribution systems
- Storage of high-alert medications in the pharmacy and on the units (for patient safety reasons)

While on the unit and visiting the pharmacy, surveyors will observe the following:
- Unit staff obtaining medications from storage through administering the medication to the patient
- Labeling of medications
- Medications available in ready-to-administer forms

Documents that may be reviewed:
- Policies and procedures to clarify or validate what staff have conveyed
- Performance measurement data related to storage of medications (for example, control of medications, inspection of storage areas, removal of medications)

B. Frequently Asked Questions, Definitions, and Additional Information About Specific Topics

Section B1: Frequently Asked Questions (FAQs)
(as of January 2009 on The Joint Commission Web site)

Updated November 24, 2008
Medication Refrigeration Temperature Logs

Q: Are we required to maintain temperature logs for medication storage refrigerators and freezers?

A: The Joint Commission does not specifically require temperature logs for refrigerators and freezers used for medication storage. Standard MM.03.01.01, EP 2, requires that medications be stored according to manufacturers' recommendations. In addition, EC 01.01.01 requires that organizations describe and implement processes to maintain and monitor equipment performance. If your organization chooses to use temperature monitoring to achieve this, the monitoring method must track temperature in an ongoing fashion to indicate whether or not internal temperature has deviated from the required ranges for all drugs stored. In addition, the organization should have a defined process outlining disposition of medication from a refrigerator or freezer that has deviated from the recommended temperature range

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Updated November 24, 2008
Sample Medications

Q. What issues must our organization consider relating to sample medications?

A. The following issues:
- Patient-specific medication information must be available in some fashion (MM.01.01.01).
- Medication must be safely stored (MM.03.01.01).
- Medication orders or prescriptions are clear and accurate (MM.04.01.01).
- The patient record contains information that reflects the patient's care, treatment or services (RC.02.01.01).
- Medications are labeled (MM.05.01.09).
- The organization follows a process to retrieve recalled or discontinued medications (MM.05.01.17).
- The organization monitors patients to determine the effects of their medications (MM.07.01.01).
- The organization responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors (MM.07.01.03).
- The organization provides patient education and training based on each patient's needs and abilities (PC.02.03.01).

Updated November 24, 2008
Security of Anesthesia Cart Medications

Q: Can an anesthesia cart containing medication be left unlocked in an OR suite between cases?

A: If the individual operating room is part of a larger OR unit that is manned at all times in a fashion that monitors access to the operating room and assures constant surveillance of the anesthesia cart to prohibit access by unauthorized individuals, locking of the cart between cases would not be required.

After hours when the OR unit is not manned in a like manner, the carts must be properly secured. Whether the carts are locked or unlocked, they must be stored in a secured area that prohibits access and tampering by unauthorized individuals (for example, in a separate locked room or in the secured OR unit where unauthorized access is prohibited).

New November 24, 2008
"Penny in a Cup"

Q. My organization uses the "penny in a cup" method for monitoring refrigerator/freezer temperature. Does this meet Joint Commission standards?

A. Health care organizations commonly freeze a small cup of water, place a penny on top of the ice, and keep the "penny in a cup" in the freezer compartment of a refrigerator/freezer unit. They surmise that as long as the penny remains on top, indicating that the ice has not melted, the refrigerator/freezer unit has remained within an acceptable temperature range.

Joint Commission standards recognize the importance of maintaining appropriate temperature ranges for both medications and nutritional products. The integrity and potency of medications, as well as the safety of nutritional products, can be compromised by temperatures that exceed recommended ranges.

The "penny in a cup" method **will not meet** the intent of Joint Commission standards for the following reasons:
1. Sensitivity—The sensitivity of this method is not proven. The temperature range of the refrigerator or freezer may be significantly above recommendations before the penny sinks. Furthermore, the penny will not recognize temperatures below the desired range.
2. Variability—The design of the refrigerator/freezer unit, as well as its maintenance, may vary significantly. A large unit, or one with a well-insulated freezer compartment, may keep the penny afloat even though the refrigerator becomes too warm. Also, surveyors commonly find freezer compartments packed with inches of ice because they have not been adequately defrosted. This thick layer of freezer ice could protect the "penny in a cup" from warming refrigerator temperatures.
3. Availability of technology—Reliable alarming and recording thermometers are readily available. Also, wireless thermometers are available that send updates to a central computer. Other options such as min/max thermometers should also be considered.

Revised November 24, 2008
Define Concentrated KCl

Q: What is considered "concentrated" in terms of potassium chloride? We have 100mL bags of potassium chloride in strengths of 20 and 40 mEq. The bag label states that it is concentrated. Must these be kept out of patient care areas? What is considered concentrated in terms of sodium chloride?

A: For potassium chloride, strengths of 2 mEq/mL or greater (specifically, vials of 20 mEq/10mL and 40 mEq/20mL) are considered concentrated. The bags noted above are not considered concentrated and may be stored in patient care areas. For sodium chloride, or NaCl, strengths greater than 0.9% are considered concentrated.

Section B2: Definition of Key Terms

Licensed repackager: A licensed repackager is a company that is licensed by the Food and Drug Administration (FDA) (and state) to repackage prescription drugs from one form of package to another. Drugs are purchased by the hospital pharmacy in bulk bottles, which are then sent to the licensed repackager, which repackages them into unit-dose packaging, returning them to the hospital pharmacy. They also can repackage drugs from a vial to a tubex or prefilled syringe.

Medication (source *CAMH* glossary): Any product designated by the Food and Drug Administration (FDA) as a drug, as well as any sample medications, herbal remedies, vitamins, nutriceuticals, over-the-counter drugs, vaccines, diagnostic and contrast agents, respiratory therapy treatments, parenteral nutrition, blood derivatives, intravenous solutions (plain, with electrolytes and/or drugs). This definition of *medication* does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases.

Ready-to-administer form: A medication that does not require preparation and can be directly administered as provided by the pharmacy or the manufacturer.

Secure (source *CAMH* glossary): In locked containers, in a locked room, or under constant surveillance. (Please note that there was discussion to add or modify the definition of *secure* to reflect the intent of the standard. This may need some work.)

Secure Area (source http://www.cms.hhs.gov/manuals/Downloads/som107ap_a_hospitals.pdf): A secure area is an area in which drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals.

Section B3: Additional Information on Specific Topics

Security of Medications

Who can have access to medications?
According to the CMS, organizations have the flexibility to define which personnel have access to locked areas based on their own needs as well as state and federal law. Organizations should define *authorized personnel* in their policies. If nonlicensed personnel have access to locked areas, controlled substances must be locked to prevent access. Organizations need to develop and implement policies and procedures to keep medications secure and minimize the risk of tampering and diversion. Staff who are allowed access to medications should be properly educated on how to perform their job with respect for the regulations. For example, housekeepers should not have keys to the locked controlled substance cabinet, but they may need to perform cleaning in the area of the cabinet.

In going through several surveys it has always been a requirement to have respiratory drugs segregated from other medications in the automated dispensing cabinets. Is this a Joint Commission standard?
Respiratory therapy and pharmacy regulations determine what medications may be accessed by respiratory therapists. If required by law and regulation, the automated dispensing cabinet should limit access for respiratory therapists to only those defined medications. The pharmacy must ensure that medications are stored in compliance with law and regulation. If law and regulation are not specific, conduct a risk assessment to guide practice. Medication management processes should be standardized for all disciplines and areas to increase compliance.

How should crash carts be stored?
The Joint Commission uses the CMS definition for medication security. In essence, a secure area for a crash cart is one in which staff are actively providing patient care or preparing to receive patients. Areas where patients and visitors are not allowed without the supervision or presence of a health care professional are also considered secure. If a crash cart with medications is in a nursing station, and there are authorized staff present who would recognize if access was breached, the cart may be considered secure for noncontrolled substances. Another example of secure would be the storage of a crash cart in a hallway that is active with authorized staff who would recognize an access breach. If the area is closed, or away from frequent monitoring, the cart would need to be secured. Conduct a risk assessment when determining placement of crash carts or other resuscitation meds, supplies, equipment (*see also* PC.02.01.11). Organizational policy may be more stringent, but not less stringent. As an additional component to ensuring quality and safety, many organizations use a numbered plastic lock that would indicate whether or not a security breach has occurred. The plastic lock does not act as a security device but rather as an indicator of quality and safety. Please keep in mind that the replacement numbered plastic locks should not be easily accessible, as that would compromise the integrity of the process. Finally, all controlled substances are required to be locked within a secure area.

Do automated dispensing machines have to be in a locked room?
The Joint Commission does not require an automated dispensing machine to be in a locked room. These units are secure because a pass code or biometric ID is required to enter them. However, each organization needs to ensure that access to the machine is limited to active, authorized staff. The organization would be expected to have a process in place to prohibit access by staff who are no longer employed by the organization.

Must medications be secured by lock even if the medication carts are in direct view of a nurse's station where staff are present?

If the medication cart is under constant supervision, and unauthorized individuals would not have access to the medications, a lock would not be required. Please keep in mind that controlled substances must be locked and stored in a manner that prevents diversion, in compliance with law and regulation.

Transportation of Medications

Who can transport medications?

Each organization can define in staff job descriptions if access and transport are allowed. Of course, this must be done with consideration for state law and regulation. The organization is responsible for the control of all medications during transport. In addition, the organization must ensure the following:

- Transport staff are appropriately trained and competent to perform their assigned functions.
- Systems and controls for medication security during transport are in place and are consistent with pharmacy policies and procedures, accepted standards of practice, and applicable pharmacy laws and regulations, (for example, using bar coding or an independent check at the points of transport and delivery).

Can the pneumatic tube system be used to transport medications?

The pharmacy must ensure that the systems and controls for medication security during transport are consistent with pharmacy policies and procedures for other medications, accepted standards of practice for medication systems, and applicable pharmacy laws and regulations. This would include, but not be limited to, the following:

- Determining whether the location for tube access would comply with medication security requirements including prevention of diversion
- Implementing security measures to prevent diversion at the point of placement in or retrieval from the tube system (for example, use of pass code)
- Defining which staff can place medications in or remove medications from the tube
- Implementing controls to ensure medication stability during transport (for example, temperature variance in the tube systems that might affect medication stability)
- Identifying any potential infection control and cross-contamination issues

How may medications be provided when the pharmacy is closed?

See also MM.05.01.13. When the pharmacy is not open 24 hours per day, the hospital must have a process for providing medications to meet patient needs. The process must include, but not be limited to, the following:

- Determining which nonpharmacist health care professionals are allowed by law or regulation and the hospital to obtain medications after the pharmacy is closed
- Implementing controls to ensure that access is limited to only trained prescribers and nurses specifically approved by the hospital
- Limiting access to only those medications approved by the hospital for access after hours, not to all medications
- Storing and securing the limited approved medications outside the full pharmacy in a secondary location (for example in a separate room, cabinet, or drawer)
- Implementing quality control checks to ensure appropriate access and prevent diversion (for example, retrieval logs, secondary checks such as bar-coding the medications retrieved or requiring an independent confirmation by another approved individual
- Arranging for a qualified pharmacist to be available to answer questions or provide medications not included in the secondary location, 24 hours per day (for example, using a pharmacist at a 24-hour location, on-call).

Carrying medications in pockets, fanny packs, and so forth
Storing and carrying medications in pockets, fanny packs, and so forth, even for a short time, may be considered problematic for several reasons. The effectiveness of the medication could be compromised by the proximity to higher body temperatures and humidity. There may also be concerns related to infection control and the potential for diversion. The organization should conduct a risk assessment and develop and implement a policy addressing the control of medication between receipt by an individual health care provider and its administration (as described in MM.03.01.01, EPs 4 and 5). If the lab coat or fanny pack was removed while containing medications, the meds may no longer be considered secure.

Definition and Dispensing of Medications

Who may dispense medications?
The Joint Commission's definition of *dispensing* appears in the *CAMH* glossary:

> Providing, furnishing, or otherwise making available a supply of medications to the individual from whom it was ordered (or their representative) by a licensed pharmacy according to a specific prescription or medication order, or by a licensed independent practitioner authorized by law to dispense. Dispensing does not involve providing an individual dose of medication previously dispensed by the pharmacy.

In addition to considering this definition, please check applicable state law and regulation for further information on who is legally able to dispense medications.

Are there any special considerations for eye clinics?
The FDA considers eye drops to be medications, and therefore all medication management standards are applicable. Please consult the manufacturer's instructions to determine if multipatient use is acceptable. If in doubt, you should consider contacting the FDA for an official interpretation. If use on multiple patients is allowable under FDA regulations, please consult your infection control practitioner in order to determine the best method for preventing cross-contamination. Additional resources could be your state's health department, pharmacy board, or hospital licensing act, which may have further regulations.

Can certified ophthalmology technicians dispense eye drops at the direction of the providers in the eye clinic? They will have training, will have demonstrated and documented competencies, and will be administering only eye drops. Does their certification need to specify medication administration, or is our training and competency assessment all that is needed?
State law and regulation will dictate the responsibilities of the ophthalmology technician. Please check your state regulations. If allowed by state law, the organization would determine the required competencies before authorizing staff to administer medications. Please refer to The Joint Commission HR standards for more information.

Concentrated Electrolyte Solutions

Which concentrated electrolyte solutions are prohibited from patient care areas?
Concentrated electrolytes should be removed from all patient care areas to eliminate accidental administration without required dilution. Concentrated electrolytes include potassium chloride 2 mEq/mL, potassium phosphate 3 mEq/mL or greater, and sodium chloride > 0.9%. Although magnesium sulfate was removed from The Joint Commission concentrated electrolyte list, it still should be considered for inclusion as a concentrated electrolyte. If stored in an area where it would be required for specific patient types, adequate precautions must be put in place. Please review the Patient Safety Practices on The Joint Commission Web site, which discuss concentrated electrolyte solutions accessibility and storage. This information includes activities that organizations should take to minimize incorrect administration of concentrated electrolyte solutions.

Can a patient care area store any concentrated electrolytes?

Each organization should determine which concentrated electrolytes should be appropriately stored in a patient care area, with consideration of patient population needs. When clinically indicated, it may be permissible to have the undiluted concentrated electrolyte available in the patient care area. The organization must ensure that precautions are in place; these include the following:

- The concentrate must be segregated from all other drugs stored in the area.
- A par level of the drug must be established so that the amount maintained on the unit does not exceed the amount necessary to meet patient care needs over a limited time period (for example, one day).
- A system for checking and restocking to par level by the pharmacy must be implemented.
- Prominent warning labels must be applied to the drug container.
- Access to the drug must be strictly limited to specially qualified staff.

Dialysate

Substances/objects are defined by the FDA as a drug, a device, or a biological. Some dialysates are also considered a combination of the two or all three of the classifications. The manufacturer must first submit an Investigational New Drug (IND) Application—for review of the solution. The manufacturer will also suggest a classification to the FDA according to the Primary Mode of Action (PMOA). This classification is further complicated by having dialysate with medication additives that should be treated as drugs. In CFR 21, Chapter 1, Subchapter H addressing GI-urological therapeutic devices (Sec.876.5630), the following text is regarding peritoneal dialysis systems and accessories. It states: "Prepackage dialysate intended for use with any of the two peritoneal dialysate delivery systems is regulated by the FDA as a drug. . . ." This information was found online with a database update listed as 4-1-08. The use of combination solutions is ever increasing. With an approval of a dialysate containing iron for therapeutic intent, it was classified as a device with a drug component. This seems to be the future trend. Because drugs, devices, and biologicals are all regulated by the FDA, the recommendation would be to treat dialysate as a medication.

Dialysate is not required to be stored by pharmacy; however, the pharmacy is still responsible for its oversight. When other departments handle medications, the pharmacy must still ensure that the systems and controls for these drugs are consistent with pharmacy policies and procedures for other medications, accepted standards of practice for medication systems, and applicable pharmacy laws and regulations.

The pharmacy is responsible for working with the other department to establish systems for ensuring the proper storage, inventory control (including checking for expired drugs and handling recalls), accountability, documentation, and distribution of these products throughout the organization. Pharmacy must also ensure that these systems are consistent with the pharmacy's medication distribution systems and that staff in the other department are appropriately trained and competent to perform those functions.

Unit-Dose Distribution/Pill Splitting

Pill splitting in the health care facility is performed when the accurate unit-dose is not commercially available. Allowing pill splitting to take place at the point of administration comes with concerns for medication errors. In the hectic environment of a patient care unit, there is always the possibility that the pill will not be split, and a patient receives twice the prescribed dose. Pill splitting in the pharmacy strictly conforms to the requirement for the most ready-to-administer form being provided to the nurse.

Pharmacy performing the pill splitting ensures that there is always an accurate and reliable pill splitter available. The pharmacy will also address the removal of residue from any previously split pills. The repackaging and labeling performed by the pharmacy adds to the safety of the process.

Joint Commission standards do not restrict pill splitting to pharmacy, but this is recommended. If the decision is to move this task to the floor so nurses can perform it, the appropriate equipment must be available, staff need to be trained, and the location where the task will take place should take into account infection control issues. In addition, the established process should include removal of residue from any previously split medication and some type of alert from pharmacy with the pill reminding the nurse that this will be split prior to dosing the patient.

Storage of Medications

How are heparin and saline flushes stored?

The FDA reclassified all forms of heparin and saline flushes as medical devices. Previously, they were classified as either a device or a drug depending on how the manufacturer submitted its application to the FDA. Their reasoning was that these products act to keep lines open as a result of a physical effect and not as a result of a chemical or therapeutic effect. In addition, the flush has no therapeutic action on the body of the patient when used as directed. Based on this reasoning and the fact that the FDA reclassified these as devices, they no longer meet The Joint Commission's definition of a medication and do not have to meet the Medication Management standards. Storage of IV flushes must be in compliance with the hospital's polices for safe storage. Caution must be taken to ensure that heparin flushes are not confused with therapeutic doses of heparin.

How should IV bags be stored?

IV solutions are considered medications and are subject to all standards in the "Medication Management" chapter, including medication security. MM.03.01.01, EP 6, speaks to medication security, stating that "the hospital prevents unauthorized individuals from obtaining medications, in accordance with the hospital's policy and law or regulation." Storage of IV bags should also be according to the manufacturer's recommendations or, in the absence of such recommendations, according to a pharmacist's instructions. All stored IV bags would require an expiration date on the label to assure the stability of the medication.

How are expired medications stored? Who can pick them up?

MM.03.01.01, EP 8, addresses expired medications: "The hospital removes all expired, damaged, and/or contaminated medications and stores them separately from medications available for administration."
When an organization stores expired medications separately, the same medication management practices for safe and secure storage apply. Expired medications should be stored in a manner that prevents diversion or inadvertent use. Individuals in the organization, authorized to do so per hospital policy and law and regulation, can pick up the expired medications to return them to the pharmacy.

Stability of Medications

What precautions should we take when we warm fluids such as pour bottles and IVs?
Accredited organizations must always ensure that the manufacturer's guidelines are followed for storage of such fluids. The package insert will provide a temperature range in which the items must be stored. For many such products, warmer temperatures result in a decreased storage time. For example, a liter IV bag might not expire for several years if stored at room temperature, but if stored at a higher temperature it might expire in only two weeks.

One of two methods is generally utilized to ensure that expired, warmed fluids are not administered to patients. Some facilities write the new, shortened expiration date on the product itself. Other facilities simply throw out all fluids left in the warmer after a given period (for example, a week) to ensure that no product is left in for too long. Whatever method is used, it is important that staff understand and adhere to the process.

Are there any special storage requirements for vaccines?
Yes. Vaccines are very sensitive to variations in temperature. It is critical that providers store vaccines to meticulously maintain the "cold chain," a shipment and storage system that ensures that active vaccine is administered. Please remember that improperly stored vaccine can result in lack of immunity for your patients. Fortunately, the Centers for Disease Control and Prevention (CDC) provides a variety of turnkey solutions to your vaccine management issues. Please visit the following Web site for free videos, books, checklists, temperature logs, and other helpful publications: http://www.cdc.gov/vaccines/recs/storage/default.htm

C: Supporting Documentation, Evidence, Value, Historical Information, and Additional References and Links
Section C1: CMS Tags, Evidence Base, and Consensus Process

Centers for Medicare & Medicaid Services (CMS) and Other Regulatory Considerations:
Link to exact language in the Federal Register.
CMS Conditions of Participation and Interpretive Guidelines, June 5, 2009:
http://www.cms.hhs.gov/manuals/Downloads/som107ap_a_hospitals.pdf.

§482.25(a)
§482.25(a)(3)
§482.25(b)

§482.25(b)(2)(i)—Nonscheduled drugs
All drugs and biologicals must be kept in a secure area, and locked when appropriate

§482.25(b)(2)(ii)—Scheduled drugs
Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.

§482.25(b)(2)(iii)—Access to locked areas
Only authorized personnel may have access to locked areas

§482.25(b)(3)

482.25 CMS Conditions of Participation: Pharmaceutical Services Definition of Secure Area
Secure area: An area in which staff are actively providing patient care or preparing to receive patients, that is, setting up for procedures before the arrival of the patient. Following are some examples:
- OR suite when staffed and staff area actively providing care—secure
- OR suite when not operational (off hours, weekends, and so forth)—not secure—all drugs would need to be locked.
- Areas restricted to authorized personnel only are generally considered secure.
- Areas where patients and visitors are not allowed without the supervision or presence of a health care professional are generally considered secure.
- L&D and critical care units are staffed and actively providing care around the clock—considered secure
- Inspect policy and procedure to ensure that these areas are secure, with entry and exit limited to appropriate staff, patients, and visitors.
- All controlled substances must be locked within a secure area regardless of whether a patient care area is staffed or actively providing patient care.
- All noncontrolled substances must be locked when a patient care area is not staffed.
- Organizations have the flexibility to define which personnel have access to locked areas based on their own needs as well as state and local law
- Organizations should define *authorized personnel* in their policies.
- May choose to include categories of staff such as housekeeping, and so forth.
- If nonlicensed staff have access to locked areas, controlled substances must be locked to prevent access.

- Organizations have the flexibility to determine the most effective way to safeguard noncontrolled drugs and biologicals when they are not locked.
- Develop and implement P&P to keep medications secure and minimize the risk of tampering and diversion.
- May choose to keep noncontrolled drugs locked.
- Or may choose to keep noncontrolled secure but not locked when area is staffed.
- P&P needs to address the security and monitoring of any carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety. (MM.03.01.01, MM.03.01.03);

CMS recognizes the value of medication self-administration and storage at the bedside:
- They reference our standards
- Need measures to secure medications at the bedside.
- Conduct a risk assessment considering roommates, visitors, type of medication, and so forth.
- MM.06.01.03 may apply.

Evidence Base and Consensus Process Used During Development

American Society of Health-System Pharmacists

1. Technical Assistance Bulletin on Hospital Drug Distribution and Control
   Available at http://www.ashp.org/s_ashp/docs/files/BP07/Distrib_TAB_Hosp.pdf (accessed Mar 13, 2013).

2. Guidelines on the Safe Use of Automated Medication Storage and Distribution Devices
   Available at http://www.ashp.org/s_ashp/docs/files/BP07/AutoIT_Gdl_StorageDevices.pdf (accessed Mar 13, 2013).

3. Technical Assistance Bulletin on Single Unit and Unit Dose Packages of Drugs
   Available at http://www.ashp.org/DocLibrary/BestPractices/DistribTABUnitDose.aspx (accessed Mar 13, 20139).

Expert Panel, Task Forces: Unknown

Field Review Process and Results: Not available for this standard

Feasibility Testing Results (Setting-Specific): Not available

Section C2: Field Testing, Value, Relationship to Measures, and Other Initiatives

Value to Field (Projected or Actual Experience)

Information not currently available.

Relationship to Performance Measures and Other Initiatives

The National Quality Forum, with support from the Agency for Healthcare Research and Quality, has identified 30 safe practices that evidence shows can work to reduce or prevent adverse events and medical errors. The 30 safe practices have been endorsed by the membership of the National Quality Forum, which includes representatives of 215 of the nation's leading health care provider, purchaser, and consumer organizations. These organizations strongly urge that these 30 safe practices be universally adopted by all applicable health care settings to reduce the risk of harm to patients. Four of the 30 safe practices, listed below, are related to elements of performance for this standard:

27. Keep workspaces where medications are prepared clean, orderly, well lit, and free of clutter, distraction, and noise.
28. Standardize the methods for labeling, packaging, and storing medications.
29. Identify all "high alert" drugs (for example, intravenous adrenergic agonists and antagonists, chemotherapy agents, anticoagulants and anti-thrombolytics, concentrated parenteral electrolytes, general anesthetics, neuromuscular blockers, insulin and oral hypoglycemics, narcotics, and opiates).
30. Dispense medications in unit-dose or, when appropriate, unit-of-use form, whenever possible.

Section C3: Historical Information and Changes

Date Standard First Implemented: Before 1970

Date(s) Updated and Reason(s) for Update: In November 2005 the Medication Management chapter underwent revisions as part of the Shared Visions–New Pathways project. MM.2.20 was included in the revisions, which resulted in the addition of two new elements of performance.

Standard and Element of Performance Crosswalk Comparing 2009 with 2008	
Standard 2009	**Standard 2008**
MM.03.01.01 The hospital safely stores medications	MM.2.20 Medications are properly and safely stored.
EP text and number in 2009	**EP text and number in 2008**
EP 2: The hospital stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions	EP 2: Medications are stored under conditions suitable for product stability.
EP 3: The hospital stores controlled (scheduled) medications to prevent diversion, in accordance with law and regulation.	EP 6: Controlled substances are stored to prevent diversion and according to state and federal laws and regulations.
EP 4: The hospital has a written policy addressing the control of medication between receipt by an individual health care provider and administration of the medication, including safe storage, handling, security, disposition, and return to storage.	EP 3: There is a written policy addressing the storage of medication between receipt of a medication by an individual health care provider and medication administration. At a minimum, the policy addresses the following: safe storage, safe handling, security, disposition of these medications including return to the pharmacy medication storage area at the end of the individual's shift.
EP 5: The hospital implements its policy addressing the control of medication between receipt by an individual health care provider and its administration.	EP 4: The policy addressing the storage of medication between receipt of a medication by an individual health care provider and medication administration is implemented.
EP 6: The hospital prevents unauthorized individuals from obtaining medications in accordance with its policy and law and regulation.	EP 5: Unauthorized persons, in accordance with theorganization's policy and law and regulation, cannot obtain access to medications.
EP 7: All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.	EP 9: Medications and chemicals used to prepare medications are accurately labeled with contents, expiration dates, and warnings.
EP 8: The hospital removes all expired, damaged, and/or contaminated medications and stores them separately from medications available for administration.	EP 7: All expired, damaged, and/or contaminated medications are segregated until they are removed from the organization.
EP 9: The hospital keeps concentrated electrolytes present in patient care areas only when patient safety necessitates their immediate use and precautions are used to prevent inadvertent administration.	EP 11: Concentrated electrolytes are removed from care units or areas (unless patient safety is at risk if the concentrated electrolyte is not immediately available on a specific care unit or area; in such situations, specific precautions are taken to prevent inadvertent administration).
EP 10: Medications in patient care areas are available in the most ready-to-administer forms commercially available or, if feasible, in unit-doses that have been repackaged by the pharmacy or a licensed repackager.	EP 12: Medications in care areas are maintained in the most ready-to-administer forms available from the manufacturer or, if feasible, in unit-doses that have been repackaged by the pharmacy or a licensed repackager.
EP 18: The hospital periodically inspects all medication storage areas.	EP 15: All medication storage areas are periodically inspected according to the organization's policy to make sure medications are stored properly.

Section C4: Additional References and Links

CMS Conditions of Participation and Interpretive Guidelines, June 5, 2009:
http://www.cms.hhs.gov/manuals/Downloads/som107ap_a_hospitals.pdf

Conditions of Participation Changes Effective January 27, 2007:
http://edocket.access.gpo.gov/2006/pdf/E6-19957.pdf

The Joint Commission: Top standards compliance issues for first half of 2007. *Jt Comm Perspect* 28:1,3,15,16, Feb. 2008.

The Joint Commission: Featured standard: Improving medication safety: How effective is your medication management system? *The Joint Commission: The Source*, 7:1, 3, May 2009.

Fine A. M.; et al.: Parent-driven technology for decision support in pediatric emergency care. *Jt Comm J Qual Patient Saf* 35:307–315, Jun. 2009.

The Joint Commission: Tracer methodology 101: The medication management tracer. *The Joint Commission: The Source* 7:6–8, Feb. 2009.

The Joint Commission: Joint Commission Resources practice leader discusses strategic safe medication management and Standard MM.01.01.01. *The Joint Commission: The Source* 6:8–10, Aug. 2008.

The Joint Commission: Reducing the risk of errors associated with concentrated electrolyte solutions. *The Joint Commission: The Source* 6:1–3, Mar. 2008.

Jennings H.R., et al.: Reducing anticoagulant medication adverse events and avoidable patient harm. *Jt Comm J Qual Patient Saf* 34:196–200, Apr. 2008.

Books

Joint Commission Resources: *The Nurse's Role in Medication Safety.* Oakbrook Terrace, IL: The Joint Commission, 2008.
http://store.jcrinc.com/the-handbook-on-storing-and-securing-medications-second-edition/

Joint Commission Resources: *Medication Management Tracer Workbook.* Oakbrook Terrace, IL: The Joint Commission, 2011.
http://store.jcrinc.com/medication-management-tracer-workbook/

Related Information

Kienle P., Uselton J.P.: Maintaining compliance with Joint Commission medication management standards. *Patient Safety and Quality Health Care,* Jul.–Aug. 2008.

Coe C., Uselton J.P.: *Assuring Continuous Compliance with Joint Commission Standards: A Pharmacy Guide,* 7th ed. Bethesda, MD: American Society of Health-System Pharmacists, 2008.

Links

U.S. Food and Drug Administration: http://www.fda.gov/
Schedules of Controlled Substances:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1308

Centers for Medicare & Medicaid (CMS) State Operations Manual:
http://www.cms.hhs.gov/manuals/downloads/som107c07.pdf

Institute for Safe Medication Practices: http://www.ismp.org

U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control:
http://www.deadiversion.usdoj.gov/schedules/schedules.htm

MALIGNANT HYPERTHERMIA RESOURCES
Malignant Hyperthermia Association of the United States: http://medical.mhaus.org/
Association of periOperative Registered Nurses: http://www.aorn.org
American Society of Anesthesiologists: http://www.asahq.org/
Centers for Disease Control and Prevention–Vaccines: http://www.cdc.gov/vaccines/recs/storage/default.htm

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